

Remarks:

Reconsideration of the application is requested. Claims 1-7, 9, and 14-24 remain in the application. No claims have been amended.

35 USC § 103

In item 2 of the Office action, the Examiner rejected claims 1-6, 8, 14-18, and 21-24 as being obvious over Malodobry (US Pub. 2004/0111107) in view of Auguste et al. (U.S. Pat. No. 6,375,977) and DeBusk et al. (U.S. Pub. 2004/0001878) under 35 U.S.C. § 103(a). As will be explained below, the claims were patentable over the cited art in their original form and the claims have, therefore, not been amended to overcome the references.

A. In reviewing the Examiner's remarks in the present (i.e. March 16, 2009) Office Action, it appears that to a certain extent the Examiner has treated the features of both the independent and the dependent claims simultaneously, which has lead to generalizations that are not applicable to the present claims. In order to clarify the underlying issues, Applicant would like to first concentrate only on the features of independent claim 1 and to comment on only the remarks of the Examiner and teachings of the cited prior art that are relative to these features. The dependent claims will be addressed separately.

B. Claim 1 defines an invention that is a method for removing pigments from a pigmented section of skin. The method comprises the following features:

- (i) puncturing the skin at said pigmented section with a skin-puncturing device provided with at least one needle;
- (ii) bandaging the punctured skin with a pad adapted to absorb the pigments and the cellular fluids;
- (iii) the pad contains one or more materials capable of accelerating a process of migration of the pigments toward an outer layer of the skin; and
- (iv) the one or more materials is a salt-based granular paste.

In other words, the method of the invention comprises two stages. The first step is to puncture the skin to mechanically destroy macrophage cells in the dermis to release the tattoo pigments trapped within the cells. The second step is to bandage the punctured area of skin. The bandage comprises a substrate comprised of a hydrophilic material, e.g. an ordinary gauze pad, whose function is to absorb the wound exudates including pigment particles. Applied to the hydrophilic substrate is a hygroscopic material, whose function is to draw the fluids and pigment fragments from the dermis to the outer layer of the skin, where they are absorbed in the substrate. The hygroscopic material is a salt-based granular paste.

“To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person.” *See* MPEP §2142.

C. Malodobry ‘107 teaches a method for removing tattoos that is based on puncturing the skin at said pigmented section with a skin-puncturing device provided with at least one needle, i.e. Malodobry ‘107 teaches feature (i) of claim 1. As admitted by the Examiner, Malodobry ‘107 does not teach feature (ii), and, therefore, also does not teach features (iii) and (iv). Thus, even assuming that a skilled person would look to the combination of the teachings of Malodobry ‘107 with Auguste et al. ‘977 or DeBusk et al. ‘878, features (ii) to (iv) must be taught in either one or both of the latter two patents.

D. Auguste et al. ‘977

(i) Auguste et al. ‘977 teaches a dressing whose role is "to absorb these fluids [i.e. the fluid exuded from deep wounds or burns] while at the same time maintaining in contact with the wound a moist environment which favors the healing process" [col. 1, lines 37-39]. During the period that the dressing is in place, it must be capable of absorbing large quantities of fluid, especially at the beginning of the period without, on the one hand, becoming over saturated such that the dressing “leaks” fluid onto the patient, his clothing,

bedding, etc. and, on the other hand, must retain enough of the exuded fluid to maintain a moist environment at the surface of the wound.

(ii) Hydrocolloid dressings are known and have been used to treat wounds for over twenty-five years. They are colloidal masses composed of gel-forming agents and are typically combined with elastomeric polymers and adhesives to form a gelatinous mass which can be applied to a backing film to form a wet or a dry bandage, which is applied to the wound. The elastomeric polymers are hydrophilic and absorb the wound exudates. As the gelling process takes place the colloidal mass becomes permeable to water vapor and, assuming that the backing film is also permeable to water vapor, excess liquid is lost allowing the dressing to be left in place for relatively long periods of time. *See for example* DeBusk et al. [0044] to [0052].

(iii) The improvement claimed by Auguste et al. '977 was to add an ethoxylated sorbitan fatty acid ester to a traditional hydrocolloid adhesive mass. According to the inventor, the addition of the ester significantly increases the permeability of the hydrocolloid mass to water vapor. Thus, the hydrocolloid mass invented by Auguste et al. '977 could be used to produce dressings that absorb wound exudates, easily and rapidly expels excess liquid to the surroundings, thus prevents over saturation, and retains moisture.

(iv) The examiner has repeated his argument from the previous Office Action that "The pad [of Auguste et al. '977] contains one or more materials adapted to accelerate the rate of absorption (or migration) within the first few hours in order to minimize the inflammatory process of healing." This is not the case. Nowhere in his patent does Auguste et al. '977 teach the addition of a material to his dressing in order to "accelerate the process of migration" of the intercellular fluids to the surface of the skin. Auguste et al. '977 presents many examples of the preparation of different embodiments of his dressing. In none of the embodiments, do the "ingredients" that comprise the hydrocolloid adhesive mass include a hygroscopic material that will accelerate the movement of liquid into the dressing. None of the dressings made by coating the

hydrocolloid adhesive mass on a backing film comprise a hygroscopic material that is applied to the dressing.

(v) The Examiner referred to col. 2, lines 1-15, of Auguste et al. '977 to support of his opinion that feature (iii) of claim 1 is taught in this patent. The Examiner appears to be confusing "hydrophilic" and "hygroscopic", which are two entirely different properties. The adjective "hydrophilic" describes a polar molecule or group that can form strong hydrogen bonds with water. The adjective "hygroscopic" describes a material that is able to absorb moisture, for example from air or from fuel.

The Applicant disagrees with the Examiner's interpretation of this passage in Auguste et al. '977 and maintains that Auguste et al. '977 is merely describing one of the (well known) problems that he is trying to solve with his invention. The solution that he proposes is presented in col. 1, lines 52-54. The solution is to incorporate an ethoxylated sorbitan fatty acid ester into a traditional hydrocolloid adhesive mass. The ester has hydrophilic not a hygroscopic properties. The addition of the ester does not accelerate the rate of absorption but rather may make a contribution to the amount of fluid that the dressing can absorb and, according to Auguste et al. '977, "Affords a significant increase in the capacity of said mass to discharge the absorbed fluids by increasing the permeability to water vapor" [col. 2, lines 61-62]. In other words, Auguste et al. '977 does not teach adding a material to increase the rate of absorption of fluid, but rather adds a material that increases the rate at which the dressing can rid itself of excess fluid.

(vi) In col. 6, line 43, in Auguste et al. '977, the use of organic polymer salts as hydrocolloids in the composition of the dressing are mentioned. It is respectfully submitted that organic polymer salts do not have the same chemical or physical properties as inorganic salts, e.g. sodium chloride. In particular, the organic polymer salts of Auguste et al. '977 are hydrophilic, i.e. they have a strong affinity for water and tend to dissolve in, mix with, or be wetted by water. Organic polymer salts are not hygroscopic, i.e. they do not absorb moisture from their surroundings, as does, for example, granular NaCl.

(vii) Accordingly, Sections D(iv) – D(vi) show that Auguste et al. '977 does not teach features (iii) and (iv) of claim 1.

E. Both the Examiner and the Applicant (section D(ii) of this response) rely upon DeBusk et al. '878 for a description of the properties. The Examiner relies on DeBusk et al. '878 specifically to demonstrate that the adhesive mass of Auguste et al. '977 can be a paste. As will be explained below, Applicant does not dispute this fact. DeBusk et al. '878 describes features (iii) and (iv) of claim 1, which are one of the types of dressing that he infuses with starch hydrosylcate and ascorbic acid to promote healing of wounds. DeBusk et al. '878 does not teach or suggest preparing a wound dressing that comprises features (iii) and (iv) of claim 1.

F. With regard to the Examiner's Response to Arguments in the March 16, 2009 Office action, Applicants apparently did not express their arguments sufficiently, thereby leading the Examiner to misunderstand or underappreciate some of them.

(i) Contrary to the impression of the Examiner, the Applicants do not contend that the hydrocolloid adhesive mass of Auguste et al. '977 is not a paste. What Applicants do contend is that, having created the hydrocolloid adhesive mass, Auguste et al. '977 does not apply any material to the mass, that would be analogous to the hygroscopic material (and specifically not analogous to the salt-based granular paste) that claim 1 requires be added to the pad of the current invention.

(ii) Contrary to the impression of the Examiner, the Applicant does not contend that the process of Malodobry '107 does not produce a wet wound. What the Applicant was arguing is that Malodobry '107 apparently did not understand the process involved in removing a tattoo and therefore did not recognize the need to accelerate the rate at which the cellular fluid and pigments are brought to the surface. At any rate, it is agreed by the Examiner and the Applicants that Malodobry '107 does not teach features (ii) to (iv) of claim 1.

(iii) The Examiner stated the following at the bottom of page 5 and top of page 6 of the March 16, 2009 Office action: "Auguste, et al. are intending to increase the amount of

exude absorbed within a time period: the first few hours after a wound is formed. This would represent an increase in the rate of absorption for this time period as compared to a conventional pad." The Applicant does not fully agree with this statement and contends that the intention of Auguste et al. '977 is to deal with the amount of exude from the wound during the time period. Auguste et al. '977 does this not exclusively by increasing the capacity of the dressing to absorb exude but also (and arguably principally) by increasing the permeability of the dressing. Based on the disclosure in Auguste, it is not possible to conclude that Auguste et al. '977 has created a dressing that has an increased rate of absorption over a conventional pad--it might simply have a more efficient mechanism for eliminating excess water.

(iv) The above quotation from the Office Action seems to be the crux of the difference of opinion concerning the relevance of Auguste et al. '977 between the Examiner and the Applicants. Despite the reservations of the Applicants as expressed in the previous section of this response, assuming *en argumendo* that the Examiner is correct and that the dressing of Auguste et al. '977 is indeed able to increase the amount of exude absorbed within a time period, this is not what the dressing of the present invention does. The dressing of the invention has been invented to increase the rate at which fluid is exuded from the wound, not the rate at which it is absorbed into the pad or the quantity of fluid absorbed. The dressing of Auguste et al. '977 is designed to cope with the fluid that is exuded from the wound and improve the natural healing process and at the natural rate. Auguste et al. '977 is not interested in interfering with the healing process by increasing this rate. This is a nontrivial and non-obvious difference between the dressing of the invention and Auguste et al. '977 and indeed all wound dressings. It is exactly this difference that accounts for the success of the method of the invention as defined by claim 1.

G. The dependent claims 2-7, 9, and 14-24 are either directly or indirectly dependent on claim 1 and therefore comprise all of the features of the independent claim.

H. None of the cited prior art teaches features (iii) and (iv) of claim 1. All of the claims are therefore inventive over the teachings of the cited prior art taken singly and in combination. *See* item 3 of the Office action.

Conclusion

In view of all of the above it is respectfully requested that the Examiner reconsider his rejections and allow the claims of the application.

Interview

Applicants request an interview with the Examiner to discuss the differences between the invention as claimed and the prior art.

Accordingly, none of the references, whether taken alone or in any combination, either show or suggest the features of claim 1. Therefore, claim 1 is patentable over the art. And, because all of the dependent claims are ultimately dependent on claim 1, they are believed to be patentable as well.

In view of the foregoing, reconsideration and allowance of claims 1-7, 9, and 14-24 are solicited. In the event the Examiner should still find any of the claims to be unpatentable, please telephone counsel so that patentable language can be substituted.

If an extension of time for this paper is required, petition for extension is herewith made.

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No fee is believed due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7640-X05-045).

Respectfully submitted,

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